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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,694	GIL-AD ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/432875.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *January 17, 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted January 17, 2007 wherein claims 1, 4, 5, 7, 9-12 and 63 are amended and claims 61, 62, and 64-69 are cancelled. This application is a continuation in part of US application 10/432875, now pending, filed September 16, 2003, which is a national stage application of PCT/IL01/01105, filed November 29, 2001, which claims priority to foreign application IL139975, filed November 29, 2000.

Claims 1-15 and 63 are pending in this application.

Claims 1-15 and 63 as amended are examined on the merits herein.

Applicant's amendment, with respect to the rejection of instant claim 10 under 35 USC 112, second paragraph, for lacking antecedent basis in the base claim, has been fully considered and found to be persuasive to remove the rejection as the base claim now includes all of the species of the dependant claim within its limitations.

The following rejections, of record in the previous office action, are maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, and 9-12 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the terms,

"phenylpropylamine **compound**," and "phenoxy-3-propylamine **derivative**," along with other similar descriptions of phenothiazine and thioxanthene compounds. It is not clear form the claims or the specification what is the full extent of compounds included within these limitations. In particular, a phenylpropylamine or phenoxy-3-propylamine compound or derivative could mean, in the present context, a molecule modified from the parent molecule by any one of a number of chemical modifications including but not limited to:

(1) Substitution of individual atoms or functional groups with equivalent atoms or functional groups.
(2) Protection of one or more functional groups with a protecting group.
(3) Attachment of one or more additional functional groups to the parent core structure.

Because the terms "compound" and "derivative" are not clearly and distinctly defined, this phrase renders the claims indefinite.

Response to Argument: Applicant's amendment, submitted January 16, 2007, has been fully considered with respect to the above grounds of rejection and not found to be persuasive to remove the rejection. The amendment substitutes the word, "compound," for "derivative," in the claims. Referring to the claimed subject matter as phenylpropylamine compounds rather than phenylpropylamine derivatives does nothing to clarify the limitations of the claimed subject matter. Therefore the rejection is maintained and made **FINAL**.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7, 8, 14, 15, and 63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising certain specific antidepressant and antipsychotic agents such as those examples explicitly recited on pp. 15-16 of the instant specification, does not reasonably provide enablement for a composition comprising any cyclic psychotropic agent, any antidepressant or antipsychotic, or any serotonin and/or noradrenaline reuptake inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a composition of matter comprising an antidepressant or antipsychotic and a topically acceptable carrier.

The state of the prior art: There are a significant number of antidepressant and antipsychotic agents known in the art. These agents have been previously combined

with appropriate carriers to produce creams, ointments, and other topical pharmaceutical compositions. However, the prior art does not provide an exhaustive listing of each and every possible chemical compound having antidepressant or antipsychotic activity, or a method of synthesizing each and every such compound. The prior art also does not indicate whether each and every possible cyclic psychotropic agent is useful as a topically acceptable composition.

The relative skill of those in the art: The relative skill in the art is high.

The predictability or unpredictability of the art: Although certain molecular targets, such as dopamine and serotonin, are known to be useful molecular targets for psychotropic agents, the brain is not fully understood to the point where the psychotropic activity or lack thereof for a particular compound may be determined in the absence of experimental data for that compound. Furthermore, the antiproliferative, analgesic, and other topical effects of psychotropic agents are not well understood to the point of being able to predict for certain whether a particular psychotropic agent possess any topical activity.

Furthermore, the art of chemical synthesis is unpredictable in that there exists no general method for synthesizing any desired compound regardless of structure. Rather, specific structures must be considered individually in order to develop an appropriate synthetic scheme.

Thus the subject matter encompassed by the claimed invention is highly unpredictable.

The Breadth of the claims: The claimed invention includes any pharmaceutical composition, such as an ointment, lotion, gel, spray, or eyedrop, comprising a cyclic psychotropic agent which is suitable for delivering the agent locally in high concentration without delivering a significant amount to systemic circulation.

The amount of direction or guidance presented: The instant specification lists a number of known cyclic psychotropic agents which are useful for treating proliferative disorders, and which could be incorporated into a topical pharmaceutical composition. No guidance is given for the discovery of novel cyclic psychotropic agents or the synthesis of candidate compounds for use in such a drug discovery program.

The presence or absence of working examples: Topical administration of psychotropic-containing pharmaceutical compositions is demonstrated in several patients on pp. 24-32 of the instant specification. No examples are given of the discovery of new cyclic psychotropic agents.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the discovery and synthesis of new psychotropic agents. See MPEP 2164.

The quantity of experimentation necessary: One of ordinary skill in the art, in order to practice the claimed invention with the full range of cyclic psychotropic agents beyond the meager number disclosed in the specification would be required to test potential compounds *in vivo* to determine whether a particular compound is useful as a cyclic psychotropic agent, as there exists no definitive *in vitro* test for psychotropic activity. Tests for antagonism of specific biological targets, such as dopamine

receptors, are not capable of identifying each and every possible psychotropic agent. According to the 2006 Chemical Abstracts catalog, The Chemical Abstracts Registry contains entries for approximately 26 million compounds, all of which are potentially included in the claimed invention if they happen to have psychotropic activity and to be cyclic according to p. 14, lines 1-6 of the instant specification. For most compounds, it is unknown whether they are or are not useful as cyclic psychotropic agents. Gathering this data for every compound known to man would involve *in vivo* screening of an enormous diversity of chemical compounds for psychotropic activity in animal subjects using models such as the rat forced swim test.

Such testing requires that the compounds to be tested be synthesized and subjected to an appropriate screening method. As described earlier, synthesis of diverse chemical structures requires novel and unpredictable experimentation in order to develop suitable synthetic methods

In vivo animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Human tests impose even greater ethical and regulatory burdens, as well as additional difficulty locating subjects. Because of the unpredictability of the art and the lack of comprehensive working examples covering any significant portion of the total number of cyclic psychotropic agents, these animal experiments would need to be repeated

hundreds of times, and involve the maintenance, killing, dissection, and disposal of thousands of experimental animals, to establish the activity or lack thereof of every possible cyclic psychotropic agent, thus presenting an a burden of undue experimentation to anyone practicing the invention with the full range of cyclic psychotropic agents claimed.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of working examples, Applicants fail to provide information sufficient to practice the claimed invention for every possible cyclic psychotropic agent.

Response to Argument: Applicant's arguments, submitted January 16, 2007, with respect to the above grounds of rejection, have been fully considered and not found persuasive to remove the rejection. Applicant argues that because the claimed active agents are limited to antidepressants and antipsychotic agents, the wide scope of potential compounds mentioned in the rejection are not encompassed by the claims, and therefore one skilled in the art would easily recognize the full scope of compounds useful in the claimed compositions. However, the claim language identifies the active agent based not on a limited, closed set of chemical structures, but rather by the open-ended functional language stating that the agent, "is selected from the group consisting

of an antidepressant and an antipsychotic agent." One skilled in the art does not know the full set of all possible chemical compounds exerting antidepressant and/or antipsychotic activities. One skilled in the art only knows certain specific agents (fluoxetine, amitriptyline, thioridazine, etc.) that have been described in the prior art as having these activities. The claims as amended do not limit the scope of the invention to only compositions containing these specific known active agents. Beyond the teaching of the prior art, any suggestion that a particular novel chemical substance is or is not useful as an antidepressant and/or antipsychotic, in the absence of actual experimental data, is purely speculative. Since the entire set of all possible chemical compounds has not been fully characterized (or even synthesized) one skilled in the art would not know which compounds are or are not included within this vast range of active agents, absent undue experimentation. Therefore the rejection is maintained and made **FINAL**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 14, 15, and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Sawynok et al. (US patent 6211171, reference of record in previous office action) Sawynok et al. discloses a composition comprising a specific tricyclic, second generation, or third generation antidepressant preferably formulated for local use, as a saline solution, cream, gel, or spray, for example, (column 4, lines 30-35, column 10, lines 37-67) as disclosed in instant claims 1-3 and 14-15. The antidepressant is preferably one of the tricyclic antidepressants including clomipramine, imipramine, or in an especially preferred embodiment amitriptyline, (column 9, line 66 – column 10 line 4) or a second or third generation antidepressant including trazodone, bupropion, or venlafaxane, (column 10, lines 33-36) as disclosed in instant claims 4-6. Although Sawynok et al. suggests that these compositions could be used for the treatment of neuropathic pain, the compositions comprise the same ingredients as those of the claimed invention disclosed to possess activity against proliferative dermatological diseases. Thus the compositions of Sawynok et al. are inherently the same as the claimed invention of instant claims 61-69. Therefore Sawynok et al. anticipates the instant claims.

Response to Argument: Applicant's arguments, submitted January 16, 2007, with respect to the above grounds of rejection, have been fully considered and not found persuasive to remove the rejection. Applicant argues that Sawynok et al. does not teach a composition for treating a benign hyperproliferative skin disorder, and thus does not teach every element of the claimed invention. However, the intended use of a composition does not serve to distinguish a composition form the prior art. If a prior art

structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, MPEP 2111.02, also e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) All that is required to anticipate the claimed invention is a composition comprising at least one active agent included within the limitations of the claimed invention, (e.g. imipramine, bupropion) in a dosage form that can be administered topically. In the instant case, Applicant's claimed composition does not differ from that of Sawynok et al. in any manner that would indicate that the composition of Sawynok et al. is not suitable for the intended use of treating benign hyperproliferative skin disorders.

Applicant also argues that although Sawynok et al. mentions topical administration, all of the recited examples involve local injection of the disclosed compositions. However, a disclosed embodiment need not be the preferred embodiment discussed by the prior art in order to anticipate the claimed invention. The fact that Sawynok et al. considers topical pharmaceutical dosage forms such as the solutions, creams, gels, ointments, and sprays discussed in column 4, line 35, indicates that Sawynok et al. anticipates the identical topical dosage forms of the claimed invention.

Therefore the rejection is maintained and made **FINAL**.

Claims 1-4, 7-15, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Beltner. (Foreign patent application EP0168626, reference of record in previous office action) Beltner discloses a composition comprising a topical ointment,

cream, or lotion containing a compound having the ability to interfere with calcium calmodulin complex. (p. 3, lines 8-12) Beltner also discloses that two compounds known to have this activity, and thus to be useful in the claimed pharmaceutical compositions, are the antipsychotic drugs fluphenazine, chlorprothixene, and clozapine, as well as the antidepressants imipramine and amitriptyline. (p. 3, lines 1-6) Although Beltner suggests that these compositions could be used for the treatment of trauma of the skin, the compositions comprise the same ingredients as those of the claimed invention disclosed to possess activity against proliferative dermatological diseases. Thus the compositions of Beltner are inherently the same as the claimed invention of instant claims 61-69. Therefore Beltner anticipates the instant claims.

Response to Argument: Applicant's arguments, submitted January 16, 2007, with respect to the above grounds of rejection, have been fully considered and not found persuasive to remove the rejection. Applicant argues that Beltner does not teach a composition for treating a benign hyperproliferative skin disorder, and thus does not teach every element of the claimed invention. However, the intended use of a composition does not serve to distinguish a composition form the prior art. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, MPEP 2111.02, also e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) All that is required to anticipate the claimed invention is a composition comprising at least one active agent included within the limitations of the claimed invention, (e.g. fluphenazine, chlorprothixene, clozapine, as imipramine, amitriptyline) in a dosage form that can be administered topically. In the

instant case, Applicant's claimed composition does not differ from that of Beltner in any manner that would indicate that the composition of Beltner is not suitable for the intended use of treating benign hyperproliferative skin disorders.

Additionally, Applicant argues that Beltner teaches a composition having a greater concentration of active ingredient that is not a therapeutically effective amount as claimed in instant claim 1. Applicant does not provide any evidence to demonstrate that these higher dosages are not therapeutically effective, either because they produce no therapeutic effect or because they cause untoward side effects. It should be noted that the possibility of side effects is less of a concern for locally administered pharmaceutical compositions than for systemically administered compositions, and that the fact that Beltner teaches administration of these compositions to the skin indicates that they are in fact safe for topical use despite their higher concentrations of active agent. Furthermore, the fact that a subject is administered a more concentrated dosage form does not necessarily indicate a higher dosage if the total amount of the composition administered is adjusted normally, or if the duration of exposure is less, for example. This is especially true for topical compositions as the total dose of active agent delivered by a topical composition is highly variable, depending on the amount administered, the condition of the subject's skin, and the amount of time the composition remains on the skin, for example. Therefore, in the absence of any definition of a therapeutically effective amount, the compositions of Beltner are reasonably considered to contain a therapeutically effective amount of active agent.

For these reasons the rejection is maintained and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 14-15, and 61-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 184-206 of copending Application No. 10/432875. (Reference cited in PTO-892, herein referred to as '875) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 184-206 of '875 anticipate the instant claims.

Claims 184-186, 197, 198, and 203-206 of '875 are drawn to a pharmaceutical composition for the treatment of proliferative skin disorders that is suitable for application to the affected skin, comprising a pharmaceutically acceptable carrier and a

psychotropic agent. Claims 187-196 and 199-202 are drawn to these compositions comprising specific cyclic psychotropic agents, anticipating the compositions of instant claims 1-10, 14-15, and 61-69. It is noted that although claims 184-206 of '875 have been withdrawn from consideration in that application, they have not been cancelled. Applicant has declined to address the merits of the above rejection. Therefore the rejection is maintained and med **FINAL**.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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